

REMARKS

I. Introduction

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. Claims 1-93 are pending in this application.

Claims 89, 91, and 93 are currently amended. New claims 94-102 are added. Support for the claims can be found in the specification as originally filed, *inter alia*, on page 4, lines 6-16 and on page 5, lines 30-33.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 89-102 are pending and under consideration in the application. Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Election/Restrictions

On page 2 of the Office Action, the PTO indicates that groups VII and VIII have been added to group VI, which now consists of claims 89-93. Applicant appreciates the PTO's willingness to combine these groups and examine claims 89-93.

b. Oath/Declaration

On page 3 of the Office Action, the PTO indicates that there is no copy of the oath or declaration available in the file wrapper. Applicants intend to submit a copy of the declaration for the file wrapper.

c. Claim Rejections – Double Patenting

Claims 89-93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 20-22, and 33-34 of U.S. Patent Number 6,703,044 as evidenced by U.S. Patent Number 5,840,332. With this response, Applicant has

submitted a timely filed terminal disclaimer under 37 CFR 1.321(c). Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claims 89, 91, and 93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 45, and 47-49 of copending Application Number 10/555,310 in view of U.S. Patent Number 5,840,332. Inasmuch as this is a provisional rejection, Applicant respectfully requests that the PTO withdraw its obviousness-type double patenting rejections. Applicant also reserves the right to take further action should the rejection become non-provisional.

d. Claim Rejections – 35 U.S.C. § 103

Claims 89-93 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent Number 6,274,171 to Sherman *et al.* (hereafter “Sherman”) in view of U.S. Patent Number 5,840,332 to Lerner *et al.* (hereafter “Lerner”). Applicant respectfully requests reconsideration and withdrawal of the rejection.

The framework for the objective analysis for determining obviousness under §103 requires:

1. Determining the scope and content of the prior art;
2. Ascertaining the differences between the claimed invention and the prior art;
3. Resolving the level of ordinary skill in the pertinent art; and
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Teleflex, Inc. v. KSR Int’l Co., 127 S. Ct. 1727, 82 USPQ2d 1385 (2007); *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

The Examiner has alleged that Sherman further in view of Lerner renders the claimed invention obvious. Specifically, the Examiner alleged that Sherman discloses an extended release dosage form of venlafaxine hydrochloride, which when in view of Lerner's delayed drug delivery device leads the skilled artisan to arrive at the instant invention. Applicants disagree.

Applicants maintain that the Examiner has failed to provide a *prima facie* case of obviousness. Applicants submit that Takeda (*Takeda Chem. Indus. et al. v. Alphapharm et al.*, No. 06-1329 (Fed. Cir. 2007), citing *KSR v. Teleflex*) notes that there must exist “a reason to prompt a person of ordinary skill in the relevant field to combine the elements the way the claimed new invention does in an obviousness determination.”

Lerner neither describes nor provides a foundation for use of his described formulations for the drug venlafaxine, or for formulation of active ingredients useful in treating depression. Sherman describes extended release formulations, however Sherman does not describe a formulation allowing for delayed burst release, as described in the subject Application. Moreover, as described in Example 11 of the subject Application, Applicants found unexpectedly, that the specific formulations utilized in the subject Application were bioequivalent to extended release formulations, at a significantly lower dose (60 versus 75 mg).

In view of the unexpected results shown herein, and the failure of the Examiner to provide a *prima facie* case of obviousness, Applicants submit that the claims are allowable.

Newly Added Claims

In this response, Applicants have added claims 94-102 which depend from one of claims 89, 91, or 93. Applicants believe that claims 94-102 are allowable by virtue of their dependency from one of independent claims 89, 91, or 93 and also because of the additional features recited in each claim.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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